

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation,	)	
and THE CURATORS OF THE	)	
UNIVERSITY OF MISSOURI, a public	)	
corporation and body politic of the State of	)	
Missouri,	)	
	)	
Plaintiffs,	)	C.A. No. 07-551 (GMS)
	)	(Consolidated)
	)	
v.	)	
	)	
PAR PHARMACEUTICAL, INC., a	)	
Delaware corporation,	)	
	)	
Defendant.	)	

**PLAINTIFFS SANTARUS AND MISSOURI'S ANSWERING BRIEF IN  
OPPOSITION TO DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS**

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## I. INTRODUCTION

It is difficult to imagine a holding more clear than “[w]e reverse the district court’s ruling that the asserted claims of the ’772 patent and claims 11 and 15 of the ’882 patent would have been obvious.” *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1358 (Fed. Cir. 2012). Nonetheless, Par Pharmaceutical, Inc.’s (“Par”) position is that when the Federal Circuit said “[w]e reverse,” *id.*, it really “did not reverse” and that “this Court’s ruling of invalidity still stands.” D.I. 207 at 1 (emphasis in original).

Par’s assertion cannot be squared with either the letter or spirit of the Federal Circuit’s mandate. This is apparent for several reasons. First, Par asks this Court to ignore the letter of the Federal Circuit’s mandate, essentially asserting that the Federal Circuit did not know how to state its own holdings. Second, by Par’s logic, the Federal Circuit’s extensive discussion of the Pilbrant and Lamers prior art, *Santarus*, 694 F.3d at 1354-57, was simply an impermissible advisory opinion because it was not intended to change the judgment of invalidity entered below. Third, the Federal Circuit’s direction that the case be remanded “for further proceedings consistent with this opinion” would make no sense if Par was correct. If, as Par asserts, the Federal Circuit had left “undisturbed” this Court’s prior judgment that the patents are invalid and thus plaintiffs take nothing, no remand was necessary and there were no “further proceedings” required.

Par’s arguments all proceed from the faulty premise that the Federal Circuit was obligated to discuss in detail the Makino and Yamasaka prior art references because this Court relied on them in its opinion as alternative grounds for finding obviousness. Par is incorrect that the Federal Circuit was obligated to discuss every aspect of this Court’s original opinion because the Federal Circuit “sits to review judgments, not opinions.” *Stratoflex, Inc. v. Aeroquip Corp.*,

713 F.2d 1530, 1540 (Fed. Cir. 1983). But Par also is wrong that the Federal Circuit ignored Makino and Yamasaka. Par does not deny that both references were briefed to the Federal Circuit, in addition to having been discussed in this Court's written opinion. Par simply overlooks the fact that the Federal Circuit did express its view on Makino and Yamasaka, albeit indirectly, when it stated that, as to the claims on which it reversed, "the *two most relevant* pieces of prior art are the Pilbrant reference and an article by Lamers . . . ." *Santarus*, 694 F.3d at 1354 (emphasis added). The Federal Circuit could not have concluded that Pilbrant and Lamers were the "most relevant" without having considered the other prior art, such as Makino and Yamasaka. That the Federal Circuit chose not to devote time and space to a discussion of prior art it perceived to be less relevant is not surprising and certainly does not support the contention that these less relevant references somehow trump the Federal Circuit's holding based on the "most relevant pieces of prior art." *Id.*

Although Par may be disappointed with the Federal Circuit's ruling, the law does not permit it a second bite at the apple. Pursuant to the mandate rule, the invalidity of U.S. Patent Nos. 7,399,772 (the '772 patent) and 6,780,882 (the '882 patent) is not at issue on remand. The other three patents, as to which this Court's invalidity holding was affirmed, are no longer asserted following filing of Plaintiffs' Third Amended and Supplemental Complaint (D.I. 203). Because the Federal Circuit has finally settled all invalidity issues, Par's motion should be denied. Plaintiffs believe that this Court, and the parties, have already devoted considerable time and resources to this dispute and ought not have to devote further resources to the recycling of issues already conclusively decided. Given the Federal Circuit's holding, the next step is to expeditiously address remedies and bring this long story to a close.

## II. NATURE AND STAGE OF PROCEEDINGS/STATEMENT OF FACTS

Plaintiffs Santarus, Inc. (“Santarus”) and The Curators of the University of Missouri (“Missouri”) commenced this lawsuit on September 13, 2007. Although Plaintiffs have asserted five patents during the course of this litigation, only two of these patents remain in the litigation: the ‘772 and ‘882 patents. After a July 2009 trial, this Court held in its April 14, 2010 opinion that “the patents-in-suit are invalid due to obviousness” and entered Judgment in favor of Par. D.I. 187 (4/14/10 Opinion); D.I. 188 (4/14/10 Judgment). In its opinion, the Court set forth five prior art grounds for its invalidity determination: U.S. Patent No. 5,840,737 (“the ‘737 patent”); Pilbrant *et al.*, “Development of an oral formulation of omeprazole,” *Scand J. Gastroenterol.* 20 (suppl. 108):113-120 (1985) (“Pilbrant”); C.B.H.W. Lamers, *et al.* “Absorption of omeprazole in Zollinger-Ellison syndrome is accelerated by alkali.” *Gut*, 26(10):A1134-35 (Abstract P129) (1985) (“Lamers”); U.S. Patent No. 5,093,132 (“Makino”); U.S. Patent No. 5,294,439 (“Yamasaka”). This Court devoted five pages of its opinion to analysis of Makino and Yamasaka as alternative grounds in support of its determination that the ‘772 and ‘882 patents were invalid as obvious. D.I. 187, at 34-38. Santarus and Missouri appealed this Court’s Judgment to the Federal Circuit on May 14, 2010. D.I. 191 (Notice of Appeal).

The question of whether this Court correctly held invalid the ‘772 and ‘882 patents as obvious over Makino and Yamasaka was briefed extensively before the Federal Circuit—references to Makino and/or Yamasaka appear over 110 times in the parties’ appellate briefing. In particular, Santarus and Par collectively devoted nineteen pages to this issue in their opening briefs. Ex. 1 (Santarus 7/20/10 brief), at 17-19, 39-45; Ex. 2 (Par 9/2/10 brief), at 25-35. Moreover, these two prior art references were discussed by both parties at oral argument. *See, e.g.*, Oral Argument at 1:15, 6:55, 18:00, and 21:10, *Santarus, Inc. v. Par Pharm., Inc.* (No.

2010-1360, -1380), *available at* <http://www.cafc.uscourts.gov/oral-argument-recordings/all/santarus.html>.<sup>1</sup>

The Federal Circuit issued its twenty-five page opinion on September 4, 2012 (slip. op., D.I. 201). It explained that “[t]he thrust of this appeal is whether the prior art discloses the claimed non-enteric coated solid pharmaceutical dosage forms.” *Santarus*, 694 F.3d at 1356. In its analysis of the claims of the ‘772 patent and claims 11 and 15 of the ‘882 patent, the Federal Circuit noted that “the two most relevant pieces of prior art are the Pilbrant reference and an article by Lamers . . . .” *Id.* at 1354. The Federal Circuit affirmed this Court’s invalidity determination as to three other patents, but reversed this Court’s invalidity determination as to the asserted claims of the ‘772 patent and claims 11 and 15 of the ‘882 patent after devoting more than six pages of its opinion to analysis of the most relevant prior art (slip. op. at 19-25, D.I. 201). It stated this holding three different times:

1. “We reverse the district court’s ruling that the asserted claims of the ‘772 patent and claims 11 and 15 of the ‘882 patent would have been obvious.” *Id.* at 1358.

2. “We conclude that the district court erred by holding that some of the thirty-six asserted claims would have been obvious over the prior art; these rulings are reversed.” *Id.* at 1347.

3. “We thus reverse the court’s obviousness holding with respect to claims 4, 5, 8, 10, 12, 14, and 15 of the ‘772 patent, which all are directed to conventional dosage forms,

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<sup>1</sup> *E.g.*, 1:19 (Chief Judge Rader: “So you were talking about Makino and Yamasaka?”); 6:55 (Mr. Chu, for Santarus: “Now the third group of prior art, the stability prior art, the Makino and Yamasaka art. It’s addressing a somewhat different problem. And both sides debate and argue how to characterize that art. . . .”); 18:07 (Ms. Carlan, for Par: “... these references, Pilbrant and Lamers, and also Makino and Yamasaka, would render those obvious as well.”); 21:10 (Ms. Carlan: “Now all of these references, Pilbrant, Lamers, and Yamasaka and Makino, what’s important is they all show that this works.”).



such as tablet or capsules, containing non-enteric coated PPIs.” *Id.* at 1355. “[W]e reverse this portion [as to claims 11 and 15 of the ‘882 patent] of the district court judgment and hold that Par did not establish by clear and convincing evidence that these claims would have been obvious over Pilbrant or Lamers.” *Id.* at 1357.

The Federal Circuit “remand[ed] for further proceedings consistent with this opinion.” *Id.* at 1358.

Par filed a Combined Petition for Panel Rehearing and Rehearing En Banc on November 12, 2012. Par’s petition for panel rehearing focused solely on urging the Federal Circuit to reconsider its reversal of the invalidity determination of the ‘772 and ‘882 patents in view of Makino and Yamasaka. Ex. 3 (Par 11/2/12 brief), at 3-11. Par’s petition for a rehearing and the accompanying petition for a rehearing en banc were denied without comment. Ex. 4 (12/17/12 Order). The Federal Circuit issued its mandate on December 17, 2012. D.I. 201.

While the appeal was pending, in about July 2010, Par commercially launched its generic versions of Zegerid 20 mg and 40 mg capsules. D.I. at 205 (Par’s Answer to Third Amended and Supplemental Complaint). Two days after the Federal Circuit issued its opinion Par “announced in a form 8-K filed with the Securities and Exchange Commission that it had ceased further distribution of its generic omeprazole/sodium bicarbonate 20 mg and 40 mg capsule product pending further developments.” D.I. 209, March 13, 2013 Joint Status Report, at 2.

On February 1, 2013, Santarus and Missouri filed a Third Amended and Supplemental Complaint, limited to the ‘772 and ‘882 patents found not invalid by the Federal Circuit. This Complaint seeks remedies based on Par’s infringement, including damages resulting from Par’s more than two years of infringing sales of its generics. D.I. 203. Despite the inclusion in the

mandate of a reversal of this Court's invalidity ruling as to the '772 and '882 patents, Par filed this Motion for Judgment on the Pleadings on March 1, 2013. D.I. 206-07.

### III. SUMMARY OF THE ARGUMENT

1. The Federal Circuit unequivocally reversed the portions of this Court's judgment that found the '772 and '882 patent to be invalid: "We reverse the district court's ruling that the asserted claims of the '772 patent and claims 11 and 15 of the '882 patent would have been obvious." *Santarus*, 694 F.3d at 1356. The Federal Circuit stated this holding plainly, several times, in different places in its opinion.

2. Par's arguments based on Makino and Yamasaka were extensively briefed to the Federal Circuit, discussed at oral argument (and, of course, addressed in this Court's original opinion). Nevertheless, the Federal Circuit expressly stated that it found Pilbrant and Lamers to be "the two most relevant pieces of prior art." *Id.* This signals that the Federal Circuit was aware of Par's other prior art arguments but did not find them persuasive. Indeed, it makes no sense to suggest, as Par does, that the Federal Circuit found the claims not obvious over the "most relevant" prior art but intended to affirm their invalidity over less relevant art.

3. Par's interpretation of the mandate would render the Federal Circuit's discussion of Pilbrant and Lamers an improper advisory opinion. Under Par's argument the Federal Circuit chose to write only about prior art references that had no effect on the outcome.

4. In any event, the Federal Circuit's opinion disposes of Par's arguments regarding Makino and Yamasaka by necessary implication. The fact that the Federal Circuit remanded for further proceedings cannot be squared with Par's interpretation of the mandate. If, as Par asserts, the judgment of invalidity remained "undisturbed," remand was unnecessary and makes no procedural sense. No further proceedings are required to leave intact an existing judgment.

#### IV. ARGUMENT

##### A. Par's Motion For Judgment On The Pleadings Is Inconsistent With The Federal Circuit's Mandate

Par attempts to turn the Federal Circuit's mandate on its head by its motion for judgment on the pleadings. The mandate finally settles the issue of invalidity. Par's motion reflects exactly the sort of unnecessary and wasteful re-litigation of issues the mandate rule (a/k/a the law of the case doctrine), was designed to avoid. *See Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1335 (Fed. Cir. 2004) ("The doctrine of law of the case was created to ensure judicial efficiency and to prevent the possibility of endless litigation.") (internal quotation marks omitted).

##### 1. It Is Well Established That The District Court Must Adhere To The Federal Circuit Mandate

"It is axiomatic that on remand for further proceedings after decision by an appellate court, the trial court must proceed in accordance with the mandate and the law of the case as established on appeal." *Bankers Trust Co. v. Bethlehem Steel Corp.*, 761 F.2d 943, 949 (3d Cir. 1985).<sup>2</sup> "The district court, on remand, [is] bound to follow that mandate; it ha[s] no authority to reconsider the issue." *United States v. Kikumura*, 947 F.2d 72, 76 (3d Cir. 1991); *see also Exxon Corp. v. United States*, 931 F.2d 874, 877 (Fed. Cir. 1991) (accord). "Thus, once a case has been decided on appeal, the rule adopted is to be applied, right or wrong, absent exceptional circumstances, in the disposition of the lawsuit." *Gindes v. United States*, 740 F.2d 947, 949

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<sup>2</sup> A threshold issue not addressed by Par is what governing law this Court should look to in making its ruling. Generally, law of the case and the interpretation of a mandate are not procedural matters unique to patent law and thus regional circuit law applies. *See Exxon*, 931 F.2d at 879. However, the Federal Circuit has also looked to its own decisional law to construe the scope of a mandate. *See, e.g., Int'l Rectifier*, 515 F.3d at 1359-60. This Court need not resolve the question of which law governs here because the case law of the Third and Federal Circuit are consistent on how to construe a mandate, as demonstrated throughout this brief.

(Fed. Cir. 1984) (internal quotation marks omitted); *Int'l Rectifier Corp. v. IXYS Corp.*, 515 F.3d 1353, 1360 (Fed. Cir. 2008) (accord).

“Where the reviewing court in its mandate prescribes that the court shall proceed in accordance with the opinion of the reviewing court, such pronouncement operates to make the opinion a part of the mandate as completely as though the opinion had been set out at length.” *Bankers Trust*, 761 F.2d at 949; *see also Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 137 F.3d 1475, 1483 (Fed. Cir. 1998) (accord). “A trial court must implement both the letter and spirit of the mandate, taking into account the appellate court’s opinion and the circumstances it embraces.” *Bankers Trust*, 761 F.2d at 949; *see also Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed. Cir. 1999) (accord).

**2. The Federal Circuit Clearly And Unambiguously Summarized Its Holding Reversing The Judgment That The Asserted Claims Of The ‘772 And ‘882 Patents Were Invalid Over The Prior Art**

Par argues, without citation to any supporting case law, that the body of the Federal Circuit’s opinion should “control” over the “Summary” and opening sections of that same opinion. Such an interpretation of an appellate opinion makes no sense and contravenes the rule that district courts must construe a mandate “in light of the opinion in its *entirety*.” *Bankers Trust*, 761 F.2d at 950 (emphasis added). The Federal Circuit’s succinct statements summarizing its holding found in at least three different places in the opinion, including the opening and “Summary” sections (quoted in Section II above) cannot be disregarded. These succinct statements were presumably meant to make it easier for the reader to understand the Federal Circuit’s holding.<sup>3</sup> In any case, they are unqualified, are not limited to particular prior art

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<sup>3</sup> Par’s own behavior bespeaks a clear understanding that the Federal Circuit found in favor of Santarus and Missouri on the ‘772 and ‘882 patent asserted claims. Two days after the opinion was issued, Par withdrew its products from the market. Section II above. That is

references, and leave no room for doubt as to the Federal Circuit's ruling. *E.g.*, *Santarus*, 694 F.3d at 1347 ("We conclude that the district court erred by holding that some of the thirty-six asserted claims would have been obvious over the prior art; these rulings are reversed."). The Federal Circuit is fully capable of summarizing its own holding. Par's invitation to find ambiguity where there is none by reading the Federal Circuit's opinion as though these summary statements did not exist should be rejected.

**3. The Body Of The Federal Circuit's Opinion Supports Its Holding And Reveals That It Considered And Rejected Alternative Grounds For Affirmance Based On Makino And Yamasaka**

Contrary to Par's suggestion, the body of the Federal Circuit's opinion fully supports the holding stated in the opening and Summary of the opinion. In fact, it reveals that the Federal Circuit considered, and was not persuaded by, Par's arguments based on Makino and Yamasaka. The body also repeats the very same holding found in the opening and the Summary.

Par does not deny that the Federal Circuit had every opportunity to consider whether the '772 and '882 patents are invalid in view of Makino and Yamasaka: this Court included detailed analysis of these two references in its opinion, the parties submitted extensive appellate briefing on this subject, and these references were even discussed at oral argument. *See* Part II, *supra*, at 4. And in its analysis in support of its holding, the Federal Circuit revealed (albeit indirectly) that it had considered and rejected Makino and Yamasaka. In addressing the asserted '772 and '882 patent claims, the Federal Circuit stated: "[t]he '737 patent is not prior art to . . . the asserted claims of the '882 and '772 patents. For these claims, the *two most relevant* pieces of prior art are the Pilbrant reference and an article by Lamers . . . ." *Santarus*, 694 F.3d at 1356

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hardly consistent with a belief that "this Court's ruling of invalidity still stands." D.I. 207 at 1 (emphasis in original). Similarly, if Par actually believed the Federal Circuit had left this Court's invalidity judgment "undisturbed" (*id.*), there was no need for it to seek rehearing.

(emphasis added). The statement “two most relevant” reveals at least two key things inconsistent with Par’s position. First, it reveals that the Federal Circuit knew of other prior art besides Pilbrant and Lamers (and the ‘737 patent, which it determined as not prior art). It makes no sense to speak of Pilbrant and Lamers as “the two most relevant” references if they were the only references the Federal Circuit considered. Second, it reveals that the Federal Circuit made a qualitative decision that Pilbrant and Lamers were more relevant than the other prior art of which it was aware. There simply is no logic to Par’s premise that having stated expressly that the two most relevant references did not render the claims obvious, the Federal Circuit nonetheless found the claims obvious, *sub silentio*, on the basis of less relevant prior art. Par’s argument does not square with what the Federal Circuit wrote. The simple, and only reasonable, interpretation is that that the Federal Circuit chose not to discuss Makino and Yamasaka by name, or in detail, because it had decided that Pilbrant and Lamers were the most relevant pieces of prior art and devoted its time to addressing those references.

#### **4. The Federal Circuit’s Opinion Should Not Be Construed As An Impermissible Advisory Opinion**

To ensure compliance with the spirit of the mandate, district courts must “[take] into account the appellate court’s opinion and the circumstances it embraces.” *Bankers Trust*, 761 F.2d at 949; *see also Engel*, 166 F.3d at 1383 (accord). Accepting Par’s argument that the Federal Circuit left “undisturbed” the finding of invalidity under Makino and Yamasaka would render the Federal Circuit’s detailed discussion of Pilbrant and Lamers no more than a whimsical academic exercise irrelevant to the ultimate issue. It is difficult to accept Par’s assertion that the Federal Circuit intentionally devoted more than six pages of its twenty-five page opinion to discussing two references that were irrelevant to the outcome (slip. op. at 19-25, D.I. 201) while simultaneously failing to discuss at all the two references on which, Par asserts, its actual holding

is based. The Federal Circuit disfavours construing a mandate in a way that renders the court's reasoning an "impermissible advisory opinion." *Engel*, 166 F.3d at 1383 ("Engel's contention that the issue of its liability under the license agreement absent infringement of the '641 patent was not before the Engel III court, if correct, would render that court's decision with respect to the validity of the license agreement an impermissible advisory opinion.").

Par's interpretation of the Federal Circuit's intent also does not square with the (uncontested) fact that the Federal Circuit **remanded** for further proceedings. If Par was right that the Federal Circuit left this Court's judgment of invalidity "undisturbed," there would have been nothing to remand. No further proceedings would be necessary (or even procedurally possible), because this Court had already entered final judgment in favor of Par and that plaintiffs take nothing. For this reason as well, Par's interpretation makes no sense.<sup>4</sup>

**5. Even If Obviousness Over Makino And Yamasaka Was Not Considered Explicitly, It Was Rejected By Necessary Implication**

Even if Par was correct that the Federal Circuit did not explicitly consider Makino and Yamasaka (as to which Par is wrong, for the reasons discussed above), the Federal Circuit nonetheless rejected Par's argument as to these two prior art references by "necessary implication." *Exxon*, 137 F.3d at 1478 ("In some cases issues not explicitly addressed by an appellate court may nonetheless be decided by necessary implication . . .").

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<sup>4</sup> Par's motion seems to be grounded in the faulty premise that this Court entered four (or perhaps more) separate "judgments" of invalidity. That is wrong as a matter of federal procedure. Par confuses this Court's reasons stated in its opinion with the single final judgment, from which appeal was taken. *See, e.g., Wellpoint, Inc. v. Comm'r Int'l Revenue*, 599 F.3d 641, 650 (7th Cir. 2010) ("The judgment is not the court's opinion or reasoning; it is the court's bottom line . . ."). The Federal Circuit need only affirm, reverse or vacate that "bottom line" judgment, not address every reason in the trial court's opinion. *See Stratoflex*, 713 F.2d at 1540 (the Federal Circuit "sits to review judgments, not opinions").

The Federal Circuit's opinion in *Int'l Rectifier* is on all fours. In that case, the district court, among other things, held that the accused devices satisfied three particular contested claim limitations, including a requirement for an "annular ring," and entered summary judgment of infringement. *Int'l Rectifier*, 515 F.3d at 1356. On the first appeal, the Federal Circuit "articulated a revised interpretation[]" of the disputed claim terms, including the "annular" limitation, and remanded for further proceedings. *Id.*

On remand, the district court held a jury trial in which it permitted the jury to consider whether the "annular" limitation was satisfied as to only some of the patents in suit, finding that the defendant had waived the right to contest that limitation in other patents for having failed to dispute it in certain required pre-trial filings. *Id.*

On the second appeal, the Federal Circuit rejected the district court's reliance on this "procedural argument" of waiver as outside the mandate because the plaintiff had "specifically raised [that argument in the first appeal], as an alternative basis for affirmance." *Id.* at 1360. The Federal Circuit further explained that although "[it] did not discuss the issue explicitly, [it] ***necessarily rejected*** all of [plaintiff's] procedural arguments . . . ." *Id.* (emphasis added). As such, the mandate "required the district court" to reject the plaintiffs' alternative procedural arguments. *Id.* at 1360 (emphasis added).

As in *Int'l Rectifier*, Par's arguments that the '772 and '882 patents are invalid in light of Makino and Yamasaka were fully briefed and argued before the Federal Circuit. *See* Section II above; *see also Consolidation Coal Co. v. United States*, 86 Fed. Cl. 384, 389-90 (2009) ("The critical factor in *Int'l Rectifier* was that the parties had fully briefed and argued the issue before the court."). And, as in *Int'l Rectifier*, for the Federal Circuit to have held that "we reverse the district court's ruling that the asserted claims of the '772 patent and claims 11 and 15 of the '882



patent would have been obvious,” it must have “necessarily rejected all” of Par’s various alternative arguments for affirmance, including Makino and Yamasaka. *Santarus*, 694 F.3d at 1358. *Int’l Rectifier* makes clear that whether or not the Federal Circuit discussed Makino and Yamasaka explicitly does not detract from its holding of non-obviousness. *See also Bayou Steel v. Evanston Ins. Co.*, 835 F. Supp. 2d 161, 169-70 (E.D. La. 2011) (in case where second argument was fully briefed but “the Fifth Circuit did not expressly reject the plaintiffs’ second argument,” finding the argument to be “implicitly rejected” and outside the scope of the mandate).

#### **6. The Cases Cited By Par Do Not Support Its Erroneous Interpretation Of The Mandate**

Not a single case Par cites supports its argument that “[i]f the appellate court fails to specifically reverse all bases for invalidity, the ultimate lower court ruling of invalidity still applies.” D.I. 207 at 6. Par’s statement is wrong as a matter of law. *See, e.g., Exxon*, 137 F.3d at 1478 (Fed. Cir. 1998) (“In some cases issues not explicitly addressed by an appellate court may nonetheless be decided by necessary implication . . . .”); *Int’l Rectifier*, 515 F.3d at 1360-61 (finding alternative arguments for affirmance raised in the briefs were necessarily rejected in view of reversal, even though Federal Circuit’s opinion “did not discuss the issue explicitly”). Neither case Par cites supports its erroneous view of the law.

In *Ecolochem*, the mandate from the prior appeal was expressly limited to one claim of the patent and the mandate was interpreted by the district court and Federal Circuit to only be law of the case as to that one claim. *See Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000) (treating claim 20 of the ‘411 patent “separately from the other claims held obvious” because its consideration of this claim in the prior appeal was law of the case). Here, the mandate “reverse[d] the district court’s ruling” as to the asserted claims of the

‘772 patent and claims 11 and 15 of the ‘882 patent. *Santarus*, 694 F.3d at 1358. Just as in *Ecolochem*, at a minimum the mandate is law of the case for those claims expressly mentioned in the Federal Circuit’s holding.

In *Taltech*, the court *vacated* (rather than reversed, as here) the district court’s holding of inequitable conduct and remanded for further fact finding as to whether certain undisclosed references were cumulative. *See Taltech Ltd. v. Esquel Enters. Ltd.*, 609 F. Supp. 2d 1195, 1200 (W.D. Wash. 2009), *aff’d in part, rev’d in part*, 604 F.3d 1324 (Fed. Cir. 2010). Because the district court’s exceptional case finding also was based “at least in part upon its finding of inequitable conduct,” the Federal Circuit also vacated the attorneys’ fees award. *Id.* The district court interpreted this directive to mean that it was free to consider, on remand, whether other grounds would justify an exceptional case. There is no such wiggle room in the Federal Circuit’s mandate in this case. Here the Federal Circuit was express in its holding as to validity of the asserted ‘772 and ‘882 claims, and reversed rather than vacating for further fact finding. Moreover, even the *Taltech* district court recognized that it would not have freedom to revisit any issue the Federal Circuit had decided by “necessary implication.” *Id.* at 1201. *Taltech* offers no support for Par’s assertion that alternative grounds of affirmance previously presented to the Federal Circuit can be used on remand to essentially undo the appellate court’s express holding.

#### **7. Par’s Motion Should Be Denied Because It Is Outside The Scope Of The Mandate**

Regardless of whether this Court believes the Federal Circuit explicitly or implicitly rejected Par’s argument as to Makino and Yamasaka, the mandate rule “require[s]” Par’s motion be denied because it seeks relief that falls outside the scope of the mandate. *Int’l Rectifier*, 515

F.3d at 1356; *see also Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1355-56 (Fed. Cir. 2009) (accord); *Engel*, 166 F.3d at 1384 (accord).<sup>5</sup>

The Federal Circuit’s opinion in *Cardiac Pacemakers* is instructive. In an earlier appeal in that case, the Federal Circuit “reinstated [a] jury verdict of validity” over the district court’s determination that the patent was obvious and remanded. *Cardiac Pacemakers*, 576 F.3d at 1353. On remand, the district court granted summary judgment of invalidity, finding the patent was anticipated. *Id.* at 1355. The district court reasoned, as Par urges here, that “[t]he Federal Circuit’s remand left open the possibility of new invalidity and unenforceability defenses,” because while the prior appeal “precluded assertion of the same obviousness argument that St. Jude had raised and lost previously, ‘St. Jude’s other theories of invalidity were not within the scope of the appealed judgment and therefore may be asserted on remand.’” *Id.* at 1354. The Federal Circuit rejected this view, finding that the district court acted outside the scope of its mandate in finding invalidity:

We agree with Cardiac that ***anticipation was not properly before the district court on remand***. In the 2004 Opinion, we clearly stated that the purpose of the remand was “for a new trial of infringement and reassessment of damages.” Furthermore, we explicitly “reinstate[d] the jury verdict of validity.” The mandate rule requires that the district court follow an appellate decree as the law of the case. *Id.* at 1356 (internal citations omitted) (emphasis added).

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<sup>5</sup> This situation is analogous to courts’ treatment of invalidity in issue preclusion cases. *See* Wright, Miller & Cooper, *Federal Practice and Procedure*, § 4478.3, at 759-60 (“As with issue preclusion, the issue [under the mandate rule] may be broader than the specific arguments addressed to the court of appeals.”). Courts teach that for issue preclusion purposes, the “issue,” is the invalidity of the patent claims and not the specific prior art references argued before the court in the prior proceeding. *See Astrazeneca UK Ltd. v. Watson Labs., Inc. (NV)*, No. 10–915–LPS, 2012 WL 5900706, 6-7, — F. Supp. 2d — (D. Del. Nov. 21, 2012) (rejecting invalidity arguments based on new prior art because invalidity is one issue for issue preclusion purposes); *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 352 F. Supp. 2d 1119, 1121 (C.D. Cal. 2005) (accord); *Roche Palo Alto LLC v. Apotex, Inc.*, 526 F. Supp. 2d 985, 996 (N.D. Cal. 2007) (accord).

In *Cardiac Pacemakers*, the district court was provided some leeway to address arguments arising from a new claim construction, though the Federal Circuit ultimately held that this latitude did not allow the district court to entertain additional challenges to the validity of the patent in suit. In contrast here, the mandate provides no authorization for Par to litigate any issues relating to invalidity. On those issues, the Federal Circuit flatly reversed, and it would be error to treat invalidity as open to further challenge.

## V. CONCLUSION

The Federal Circuit has made clear, not once, or twice, but three times that it disagrees with Par's validity challenges as to the '772 and '882 patents and therefore reversed that aspect of this Court's judgment. The question of validity is no longer one that Par is permitted to debate. As even Par concedes, a decision against it on the present motion disposes of any defenses it has on the merits and leaves only remedies to be determined. D.I. 209, March 13, 2013 Joint Status Report at 3 ("[I]f the final ruling on Par's motion for judgment on the pleadings does not favor Par, the only issue in the case is a determination of any damages."). Plaintiffs respectfully request that the Court deny Par's motion so that this case can proceed efficiently to the remedies phase, which is all that remains open following appeal.

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March 18, 2013

**CERTIFICATE OF SERVICE**

I hereby certify that on March 18, 2013, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.


I further certify that I caused to be served copies of the foregoing document on March 18, 2013 upon the following in the manner indicated:

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